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10/506,904	09/07/2004	Yehoshua Yeshurun	1975/43	7073

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EXAMINER

SMITH, PAUL B

ART UNIT PAPER NUMBER

3763

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/506,904

Applicant(s)

YESHURUN ET AL.

Examiner

Paul B. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 26-52 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-12 is/are allowed.
- 6) ☒ Claim(s) 13-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see page 9, filed 8/23/2006, with respect to objections of claims 1, 2, 11, 13, 14, 24, 26, 32 and 46 have been fully considered and are persuasive. The objection of claims 1, 2, 11, 13, 14, 24, 26, 32 and 46 has been withdrawn.
2. Applicant's arguments see page 10-11, filed 8/23/2006, with respect to claims 1-12 have been fully considered and are persuasive. The rejection of claims 1-12 has been withdrawn.
3. Applicant's arguments, see page 10-11, filed 8/23/2006, with respect to the rejection(s) of claim(s) 13 under U.S.C. 102 (b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Gerstel *et al.* ('482).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 13 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstel *et al.* ('482).

6. Gerstel *et al.* discloses a method for transporting fluid across a biological barrier comprising providing a substantially planar surface (14) with a plurality of microneedles (12) with conduits (18), positioning the device in contact with a biological barrier, and scarifying said biological surface. (See Figure 1) Where scarifying is defined as scratching or cutting the biological barrier. (See Column 2 Lines 24-26) It is inherent that scratching or cutting would involve a path of movement having a non-zero component.

7. Gerstel *et al.* appears to reasonably disclose every element of claim 13.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 14-18 rejected under 35 U.S.C. 103(a) as being unpatentable over Grestel *et al.* ('482) in view of Tobinaga ('463).

11. Gerstel *et al.* discloses a method for transporting fluid across a biological barrier comprising providing a substantially planar surface (14) with a plurality of microneedles (12) with conduits (18), positioning the device in contact with a biological barrier, and scarifying said biological surface. (See Figure 1) Where scarifying is defined as scratching or cutting the biological barrier. (See Column 2 Lines 24-26) It is inherent that scratching or cutting would involve a path of movement having a non-zero component.

12. Gerstel *et al.* fails to disclose specific microneedle configurations.

13. Tobinaga teaches microneedles being asymmetrical such that a base-to-tip vector is non-perpendicular to the planar surface. (See Figure 14a-c) Tobinaga further teaches that the projection of the penetrating tip onto the planar surface lies within the base area of the microneedle. (See Figure 1) Tobinaga discloses microneedles formed with at least one sidewall standing substantially perpendicular to the planar surface and at least one wall inclined relative to a perpendicular to the planar surface. (See Figure 8)

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Tobinaga further discloses microneedles formed with at least two sidewalls each having a substantially planar face and being positioned such that an angle between the faces is between 30° and 70°. (See Figure 14a and 14c)

14. It would have been obvious to one of ordinary skill in this art at the time the invention was made to have incorporated the teachings of Tobinaga with those of Gerstel *et al.* to provide microneedles that were capable of penetration for a transdermal delivery of fluid.

15. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel *et al.* ('482) in view of Peterson *et al.* ('163).

16. Gerstel *et al.* discloses a method for transporting fluid across a biological barrier comprising providing a substantially planar surface (14) with a plurality of microneedles (12) with conduits (18), positioning the device in contact with a biological barrier, and scarifying said biological surface. (See Figure 1) Where scarifying is defined as scratching or cutting the biological barrier. (See Column 2 Lines 24-26) It is inherent that scratching or cutting would involve a path of movement having a non-zero component.

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17. Gerstel *et al.* fails to disclose a flow actuation mechanism that generates a driving pressure of at least 1,000 PSI to produce a high velocity fluid jet emerging from the conduits.

18. Petersen discloses a device that generates a driving pressure of about 1,200 PSI to 1,800 PSI to deliver the medicate by a high velocity fluid jet generated by force applied manually to the flow actuation mechanism. (Column 19, Line 50)

19. It would have been obvious to one of ordinary skill in this art at the time of the invention was made to have incorporated the teachings of Peterson with those of Gerstel *et al.* to provide a device for transporting fluid across a biological barrier with a high velocity fluid jet.

20. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel *et al.* ('482) in view of Palmer ('242).

21. Gerstel *et al.* discloses a method for transporting fluid across a biological barrier comprising providing a substantially planar surface (14) with a plurality of microneedles (12) with conduits (18), positioning the device in contact with a biological barrier, and scarifying said biological surface. (See Figure 1) Where scarifying is defined as scratching or cutting the biological barrier. (See Column 2 Lines 24-26) It is inherent

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that scratching or cutting would involve a path of movement having a non-zero component.

22. Gerstel *et al.* fails to disclose an abutment surface.

23. Palmer discloses a device for penetration of a member for the intradermal sampling or administration of a substance consisting of a planar surface (22), a plurality of microneedles (43), and an abutment member (48). The path of movement of the microneedles has a non-zero component parallel to the planar surface relative to the abutment member. Each microneedle is formed with a conduit (40) extending from the penetrating tip through the bottom wall (22) to the cavity (24). (See Figure 3) The path of movement for the device carries the planar surface (22) from an initial position above the abutment member (48) to a deployed position below the abutment member (48). (See Figure 5) The abutment member (48) encircles the fluid transport configuration (12) initially and deployed. (See Figure 4) Palmer teaches that an adhesive can be applied to abutment member (48) to grip the barrier membrane. (See Column 8, Lines 12-15)

24. It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Gerstel *et al.* with the teachings of Palmer to provide an abutment surface.

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25. Claims 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel *et al.* in view of in view of Eppstein ('611) and in further view of Paul ('783).

26. Gerstel *et al.* discloses a method for transporting fluid across a biological barrier comprising providing a substantially planar surface (14) with a plurality of microneedles (12) with conduits (18), positioning the device in contact with a biological barrier, and scarifying said biological surface. (See Figure 1) Where scarifying is defined as scratching or cutting the biological barrier. (See Column 2 Lines 24-26) It is inherent that scratching or cutting would involve a path of movement having a non-zero component.

27. Gerstel *et al.* fails to disclose a vibration generator to enhance the penetration of the microneedles.

28. Eppstein teaches enhancement of transdermal delivery with ultrasound. (See Abstract)

29. Paul discloses a drive structure for reciprocating a tattoo needle. (See Abstract)

30. It would have been obvious to one of ordinary skill in this art at the time the invention was made to have used the disclosure of Gerstel *et al.* with the teachings of

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Eppstein in conjunction with the device disclosed by Paul to provide a vibration generator capable of enhancing penetration of microneedles into the biological barrier.

Allowable Subject Matter

31. Claims 1-14 are allowed.

Conclusion

32. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

33. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is 571-272-6022. The examiner can normally be reached on 8 am - 4 pm.


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35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

36. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul B Smith
Examiner
Art Unit 3763

PBS
October 31, 2006


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